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EXAMINER	
GAKH, YELENA G	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/737,185	BOWMAN ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,38 and 40-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 38 and 40-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In response to the Appeal Brief filed on 11/21/05 the examiner withdraws the finality of the last Office action and makes some changes in the grounds for rejections for clarification purposes. Claims 1-21, 38 and 40-44 are pending in the application.

Double Patenting

2. Applicant is advised that should claims 1-7 be found allowable, claims 9-16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). "A diagnostic specimen system" is not structurally different from "a toxicology specimen system" in any way.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-21 and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All independent claims recite "a diagnostic specimen system comprising a population of biomedical specimen collection vessels" with the members of the population located in three different locations (a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory). According to 35 U.S.C. 101, patentable inventions are related to "any new and useful process, machine, manufacture, or composition". It is not clear, which category of this four the claimed subject matter belongs to. Also, "the subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined.

As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. *Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.* The following are examples of language *that may raise a question as to the limiting effect of the language in a claim*: (A) statements of intended use or field of use, (B) "adapted to" or "adapted for" clauses, (C) "*wherein*" clauses, or (D) "whereby" clauses" (MPEP, Chapter 2106). It is not apparent, what particular structure of the diagnostic specimen system is recited in the claims, besides a particular structure recited for collection vessels. Location of a part of the system at a specific place cannot be considered "a particular structure" of the diagnostic system. Moreover, it is not clear, what will happen to the subject matter of the claim, if a part of the system, after being located at the specific location for some time, will be on the way to a different location (e.g. disposal), or on the way from the manufacturing site. Also, it is not clear, if the diagnostic system manufactured at the manufacturing site and still located at that site belongs to the claimed subject matter of the instant application. Furthermore, it is not clear, if the same vessels should always be present at these particular locations, or these vessels are moving from one place to another? If the vessels are moving and changing their location, then how can such system be definite? Besides that, the vessel distribution facility (shelves with the vessels), the specimen collection facility (a special restricted area in the laboratory) and the specimen testing laboratory can be the same place.

The examiner concludes that since the location of the vessels does not further limit their structure, the limitation recited in the independent claims after "wherein" (excluding the structural elements related to the vessels themselves) does not bear any patentable weight. Moreover, as it was indicated, all three "facilities" can be located in the same room: a bench with the vessels comprising tags being "a distribution facility", a special place for collecting samples, e.g. a restroom, being "a specimen collection facility", and a specimen testing laboratory being a lab in the same room. These definitions meet requirements for all claims except for claim 18.

Claim 18 is indefinite as to which data are stored at the vessel distribution facility.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1-4, 6-7, 9-12, 14-15, 19, 21, 38, 40-41 and 44** are rejected under 35 U.S.C. 102(e) as being anticipated by Petrick (US 6,535,129B1).

Petrick discloses a method and a business form attached to a collection vessel for establishing a chain of custody; the invention comprises using a population of biomedical specimen (including toxicology specimen) collection vessels, each having wireless electronic memory tag 106 attached to the vessel for non-contact storage and retrieval of information; the tag includes a radio frequency transponder and stores identification code for the vessel (col. 3, lines 18-36), as well as the information corresponding to the various forms 102: "in one example embodiment, RFID logger 108 may prompt the collection (or other) custodian 54 to input additional required information either manually (e.g., by writing the information onto form 102 using a pen or pencil) and/or **automatically (e.g., by inputting information into a computer workstation or other electronic device via a keyboard, barcode scanner, optical character reader, speech recognition device and/or other data input means) (block 206)**. This additional information may become part of form 102 and/or a data record 110 that RFID logger 108 (and/or chip 106) records. RFID logger 108 may record the collected information onto form 102 and/or in an associated data record 110 (block 208)--which data record is associated with the particular RFID chip 106" (col. 3, lines 66-67 and col. 4, lines 1-12). Several types of forms are disclosed, which include information on a donor, a specimen and lab work required for the specimen, which all may be entered both manually and electronically. The specimen system

further includes a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel (the label of US 5,976,014 recited by Petrick in col. 1, line 60 and col. 3, line 10), the label also serving as a tamper-indicating seal. The information is shared between different remote users: "as shown in FIG. 1, one interesting capability provided by system 50 is the ability to exchange data records 110 between custodian sites. For example, each RFID logger 108 may be coupled to the Internet, an enterprise intranet, a local or wide area network, the telephone network, or other data network 112. Data network 112 allows the various data loggers 108 to share automatically collected information and/or record the collected information to a centralized or distributed database facility 114 for archival and management purposes. Data network 112 allows data records 110 associated with an RFID chip 106 to "follow" the RFID chip in the sense that any node connected to the network may (if authorized) access a record tagged to the RFID chip" (col. 4, lines 45-57). The method for recording information includes providing a population of biomedical specimen containers, which a collection custodian receives from a distribution location (see Figure 1), collecting a specimen from a donor in the specimen container at the specimen collection facility and electronically storing information about the specimen, donor, and/or test to be performed in the specimen on the electronic memory tag (col. 3 and 4).

6. **Claims 1, 6-7, 9, 14-15, 19, 21, 40-41 and 44** are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen system comprising a plurality of biomedical specimen collection vessels (test tubes) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col.

2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

"A population of " biomedical specimen collection with "members" located at various locations of the specimen path is an inherent feature of the invention. As soon as the tag becomes attached to the test tube, the location where it occurs becomes "a distribution facility". Attaching the tag with all information should occur before collection of the sample into the vessel. The expression "said labels are mounted on supports being provided to fix said labels onto said test tubes during the time of analysis" obviously refers to analysis in general. The situation, when the tubes are used for collecting samples without providing any information related to the sample and "the person under concern" (col. 1, line 68) seems improbable. The system inherently includes an electronic database accessible from the specimen collection facility for storing data entered at the collection facility. Exchanging information between the collection of vessels and a remote location inherently comprises an electronic network. Berney discloses a method for recording information about a diagnostic specimen by providing a population of biomedical specimen containers with wireless electronic memory tags, distributing these containers to a specimen collection facility, collecting samples and electronically storing information about the specimen, donor, and/or tests to be performed, as it is indicated previously.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney.

Although Berney did not specifically disclose transporting vessels with collected specimen to a specimen testing laboratory, transporting such vessels from the collection site to the lab is a conventional medical practice. It would have been obvious for any person of ordinary skill in the art to imply conventional practice for Berney's vessels, because it allows tracking the vessels using Berney's inventive electronic tags on the specimen vessels.

11. **Claims 5, 8, 13 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of the prior art disclosed by Leuenberger (US 5,314,421).

Although Petrick or Berney do not specifically disclose storing data including the identity of a supplier of vessels and product information, such information is conventionally provided for all manufactured products, including test tubes (vessels, containers). Also, Leuenberger who discloses blood plastic containers indicates in the "Background of the Invention": "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, *manufacturer's product code* and *lot number*, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product and product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and also because information on a supplier and the product is always conventionally provided with all manufactured products, especially test tubes (vessels, containers).

It would have been obvious for any person of ordinary skill in the art to store this information before collecting the samples into the vessels. It would have been obvious for any person of ordinary skill in the art to ship members with electronically stored data to the specimen collection facility, because shipping test tubes from a distribution facility to a specimen collection facility with information on manufacturer/supplier and the test tubes is a conventional step in diagnostic environment, and upgrading this system by electronically storing this information is obvious for Petrick's or Berney's test tubes, which are specifically designed for handling such information.

12. **Claims 16-17, 20, 42 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrick or Berney in view of Hoffman et al. (US 5,613,012) or Fukuzaki (US 5,948,103).

Petrick or Berney do not particularly teach encoding electronic signature in the electronic tag, although Petrick specifically indicates "tester's signature" in form 102, Fig. 3B. The signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Petrick's or Berney's system, specifically for the reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

13. **Claims 2 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

14. **Claims 3-4 and 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Stevens et al. (EP 1,004,359 A2).

Berney does not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container.

15. **Claim 38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman (US 5,135,313).

Berney does not specifically disclose the vessel with a tamper-indicating seal.

Bowman discloses a chain-of-custody tamper-indicating seal for a bag for sealing a specimen taken to a remote location.

It would have been obvious for anyone of ordinary skill in the art to modify Berney's specimen collection vessel with tamper-indicating seal disclosed by Bowman for the same reasons indicated by Bowman, i.e. "so that any attempted tampering with the specimen will be indicated by at least a partial destruction of the seal" (col. 1, lines 7-8).

16. **Claim 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens and Leuenberger.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all

useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2).

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to modify Berney container (test tube) by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A

Berney in view of RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for any person of ordinary skill in the art to add a label with a barcode and provide the same information to the electronic tag in the same way Stevens labeled

his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container

Berney in view of RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier and the product (container) information.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for any person of ordinary skill in the art to add information on identity of suppliers as indicated by Leuenberger, because this conventional information is always provided with the manufacture products, especially the test containers, and because the identity of the supplier and the vessel may assist in the proper handling the vessel.

17. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens, Leuenberger the same way it is applied to claim 8 above, and further in view of Hoffman or Fukuzaki.

Berney in view RD 421048 A, Stevens and Leuenberger do not particularly teach encoding electronic signature in the electronic tag, although the signature of the "person under concern" (Berney, col. 1, line 68) is conventional for all forms related to testing biological samples.

Hoffman teaches using an electronic signature (col. 32) in a "tokenless identification system for authorization of electronic transactions and electronic transmissions" (Abstract), with the electronic signature securing electronic transactions.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skill in the art to incorporate encoded electronic signature of the type disclosed by Hoffman or Fukuzaki for securing electronic transactions into Berney- RD 421048 A-Stevens-Leuenberger's system, specifically for the

reasons indicated by Hoffman and Fukuzaki, i.e. for securing electronically transferred data, and because the signature of "the person under concern" is conventional in all diagnostic procedures.

Response to the Applicants' Arguments

18. Applicant's arguments filed with the Appeal Brief on 11/21/05 have been fully considered but most of them are moot in view of the revised rejections. The examiner responds to the arguments, which are still relevant to the present Office action.

Regarding Applicant' patentable invention *vs.* Petrick's US 6,535,129.

In response to the Applicants' remark that the examiner was supposed to recite MPEP §2308.01 in the first Office action citing Petrick as an anticipatory reference under 102(e), the examiner would like to notice that this section of MPEP refers to Interference Proceedings and is not routinely cited in first Office actions. The examiner properly cited a corresponding paragraph from MPEP as the response to the Applicants' submission of the 1.131 Declaration.

The same is true regarding further recitation of MPEP §2308.01 related to "the counts of interference". No "Interference Proceedings" were invoked at this stage of the prosecution.

Further, in their arguments related to comparing their invention with the one of Petrick, the Applicants make a statement that the examiner does not quite understand. On page 10 of the Appeal Brief the Applicants state: "If Applicant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions. If not, the parties are not claiming the same patentable invention". It appears that there is no case when the Applicants' and Petrick's inventions can be the same. Contrary to this statement, the examiner indicates that the inventions are the same because Petrick *claims* a business form comprising a wireless electronic memory tag *attached* to a vessel (claim 7), while the Applicants claim a population of vessels with attached business forms (the wireless electronic memory tag). Since the claims are interpreted in light of the specification, and the specification discloses a plurality of medical samples, Petrick's business form attached to the vessel is actually a population of business forms attached to a population of vessels or, which is the same, a population of vessels with attached

business forms. As the examiner have indicated in the previous Office actions, the location of the claimed vessels does not bear any patentable weight. Since the vessels are not chained to their locations and are in a constant move, their location is not a structural limitation to the system disclosed. Moreover, contrary to the Applicants' statement, the vessels cannot be located at the specific locations all the time, because they are transported from one location to another, which destroys patentability of the population of vessels: if the whole group of vessels is transported from one specific location to a different specific location, the patent would be invalid for the time period of their transportation.

The Applicants further state that their claim "does not *disclose* [Examiner] or suggest a business form (much less one having two portions) or any particular relationship between such a form and an identification device". Reading the Applicants' claims in light of their specification, namely, "an electronic memory tag 3 is affixed to an exterior surface of the vessel 1. An enlarged front view of a preferred embodiment of the electronic memory tag 3 is shown in FIG. 2. The electronic memory tag 3 includes a carrier label 4, which has a front face 5 and a rear face 6. Preferably, the front face 5 is imprinted with an identification bar code 7. A text area 8 is also provided for printing, typing, or writing pertinent information on the front face 5 of the carrier label 4. A detail view of the rear face 6 of the carrier label 4 is shown in FJG.3. An electronic memory device 9 is attached to the rear face 6. Alternatively, the invention may include a separate electronic memory tag 3 and a second printed label having a bar code 7 imprinted thereon (not shown)" (page 11), any routineer in the art can come to a conclusion that this description exactly reflects Petrick's business form.

Reading Petrick's claim reciting the business form with the wireless electronic tag attached to the vessel in light of the specification, any routineer in the art can conclude that this is the Applicants population of vessels located in specific locations, such as a distribution site, a collection site, an analytical site (lab), etc. The examiner is not aware of a practice of comparing only first independent claims in determining closeness of two inventions recited in the claims. Moreover, the Applicants statement that just a mere classification of inventions in different classes unambiguously indicates that they are patentably distinct, is not quite correct, which is confirmed by the Applicants' own application. While it contains two separate groups of claims

directed to a specimen system and a method for recording information, classified in different classes, they are not patentably distinct, and therefore were not restricted.

Regarding claim 18 and "a method for electronically storing information"; it is not quite clear to the examiner, why the Applicants refer again to claim 7 of Petrick's patent, when claim 8 of the patent specifically recites "a method of establishing a chain of custody", essentially repeating the Applicants' "method for electronically storing information".

The Applicants' conclusion that the examiner did not specify "what the count or counts of an interference would be" because "the task is impossible" is not correct. The examiner did not specify the counts, because the application was not in the stage of interference, and it was not the examiner's responsibility to do so at this stage of the prosecution. However, as the examiner demonstrated in this response, the Applicants' invention is not different from Petrick's; and taking into account a very short difference in the filing dates of the application and the patent, the Declaration under 1.131 is not valid in this case.

Rejections under 112, second paragraph.

The Applicants state that the "claims cover a manufacture". The manufacture in this case is a vessel (or a plurality of vessels) with an electronic tag. Location of the vessels is not a manufacture. The location does not belong to any statutory classes cited by MPEP. If the Applicants meant to claim "a specimen container supplier, a specimen collection site, and a laboratory" shown on Figure 5, such invention would hardly have any statutory basis. The Applicants' reference to Figure 5 demonstrating these sites is not apparent to the examiner. While the Applicants state that "the language describes subject matter with a reasonable degree of clarity and particularity", the examiner cannot agree with such statement. As it was indicated many times before, it is not apparent to the examiner, how the scope of the claims and patentability of the claimed subject matter as a whole can be time-variable. The examiner questioned the Applicants regarding patentability of the invention in the case, when the whole batch of the vessel is transported from one specific location to another specific location. Does it mean that the patent becomes invalid for the time period of their transportation?

In conclusion of this section, the Applicants failed to demonstrate, which class of the statutory subject matter the location of a group of vessels belongs to.

Regarding rejection over Petrick under 102(e). Petrick unambiguously discloses "an unbroken chain of custody". All locations recited in the Applicants' claims belong to the "unbroken chain of custody". Moreover, as the examiner indicated before, "Petrick's reference disclosing a population of vessels of the same structure as the one disclosed in the instant invention and having the same practical utility inherently comprises all features of the system, including distribution of the vessels at appropriate facilities. Even a simple drawing in the patent (Figure 1) demonstrating a chain "collection custodian" - "intermediate custodian" - "laboratory", etc., indicates the distribution of the vessels within these facilities". Moreover, the examiner demonstrated that Petrick is the prior art, and therefore the rejection is sustained.

Regarding anticipatory rejections over Berney under 102(b). The examiner believes that the Berney's expression "at the time of analysis" does not mean that the electronic memory labels with the sample information are attached to test tubes *after* the sample is collected and is transported to the lab for analysis. The examiner thinks that Berney's "time of analysis" is a generalized expression indicating that the samples are to be analyzed. It is hard to imagine the situation, when the samples are collected in a plurality of vessels, with no information on the samples provided with the vessels, and are transported to the test laboratory as anonymous samples to be labeled "at the time of analysis". The examiner believes that this is an unintentional misinterpretation of Berney's disclosure by the Applicants. Again, the Applicants refer to the location of the vessels, which the examiner does not consider a structural limitation of the claimed invention. Berney discloses a plurality of vessels with attached electronic tags, which comprise information on a patient, analysis, etc. There is no way such tag can be attached to the test tube *after* the collected sample was transported to the test lab.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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1/4/06

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